

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X	
NICOLE PERRY,	:
	:
Plaintiff,	:
	:
-against-	: Case No. 08 CV 01969
	:
	: ECF Case
JOHNSON & JOHNSON, JOHNSON &	:
JOHNSON PHARMACEUTICAL	:
RESEARCH & DEVELOPMENT, L.L.C.,	: <b>DEFENDANTS' ANSWER,</b>
f/k/a R.W. JOHNSON PHARMACEUTICAL	: <b>AFFIRMATIVE DEFENSES AND</b>
RESEARCH INSTITUTE, and ORTHO-	: <b>JURY DEMAND</b>
McNEIL PHARMACEUTICAL, INC.	:
	:
Defendants.	:
-----X	

Defendants Ortho-McNeil Pharmaceutical, Inc., now known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil"), Johnson & Johnson ("J&J"), and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("J&JPRD"), (collectively referred to herein as "Defendants"), by and through their undersigned counsel, hereby respond to the Complaint (the "Complaint") filed by Plaintiff Nicole Perry (referred to herein as "Plaintiff") as follows:

**NATURE OF THE ACTION**

1. Defendants deny the allegations contained in Paragraph 1 of the Complaint.
2. In response to Paragraph 2 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product know as ORTHO EVRA®. Defendants deny all remaining

allegations contained in Paragraph 2 of the Complaint.

**PARTIES, JURISDICTION AND VENUE**

3. The allegations of Paragraph 3 are conclusions of law to which no response is required. To the extent an answer is required, Defendants state that they have no knowledge as to where Plaintiff resides and therefore are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint.

4. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 4 of the Complaint.

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent an answer is required, Defendants state that they have no knowledge as to where Plaintiff resides and therefore are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 5 of the Complaint.

6. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 6 of the Complaint.

7. Defendants admit the allegations contained in paragraph 7 of the Complaint.

8. In response to Paragraph 8 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 8 of the Complaint.

9. In response to Paragraph 9 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 9 of the Complaint.

10. In response to Paragraph 10 of the Complaint, Defendants state that J&J is a

holding company that does not manufacture or sell any products in the State of New York.

Defendants therefore deny the allegations contained in Paragraph 10 of the Complaint.

11. In response to Paragraph 11 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York.

Defendants therefore deny the allegations contained in Paragraph 11 of the Complaint.

12. Defendants admit that J&JPRD is a New Jersey limited liability company with its principal place of business in New Jersey. Defendants otherwise deny the remaining allegations contained in Paragraph 12 of the Complaint.

13. In response to Paragraph 13 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the remaining allegations contained in Paragraph 13 of the Complaint.

14. Defendants admit the allegations contained in Paragraph 14 of the Complaint.

15. Defendants deny the allegations contained in Paragraph 15 of the Complaint.

16. In response to Paragraph 16 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 16 of the Complaint.

17. In response to Paragraph 17 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 17 of the Complaint.

18. In response to Paragraph 18 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 18 of the Complaint.

19. In response to Paragraph 19 of the Complaint, Defendants admit that Ortho-McNeil Pharmaceutical, Inc. was a Delaware corporation with its principal place of business in New Jersey, and that Ortho-McNeil-Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey. Defendants otherwise deny the allegations contained in Paragraph 19 of the Complaint.

20. In response to Paragraph 20 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the remaining allegations contained in Paragraph 20 of the Complaint.

21. In response to Paragraph 21 of the Complaint, Defendants admit that Ortho-McNeil Pharmaceutical, Inc. was a subsidiary of J&J and Ortho-McNeil-Janssen Pharmaceuticals, Inc. is a subsidiary of J&J. Defendants otherwise deny the remaining allegations contained in Paragraph 21 of the Complaint.

22. Defendants admit the allegations contained in Paragraph 22 of the Complaint.

23. Defendants admit the allegations contained in Paragraph 23 of the Complaint.

24. Defendants admit the allegations contained in Paragraph 24 of the Complaint.



**FACTUAL ALLEGATIONS**

25. In response to Paragraph 25 of the Complaint, Defendants admit that ORTHO EVRA® is a combination transdermal contraceptive patch which is available by prescription for the prevention of pregnancy.

26. In response to Paragraph 26 of the Complaint, Defendant Ortho-McNeil admits that on the Ortho-McNeil Pharmaceutical, Inc. web site, it states that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in women's health care. Ortho-McNeil offers the broadest range of prescription birth control options..." Defendants otherwise deny the allegations contained in Paragraph 26 of the Complaint.

27. Defendants admit the allegations contained in Paragraph 27 of the Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.

29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

30. Defendants admit that Ortho-McNeil submitted a New Drug Application for approval by the FDA of ORTHO EVRA® as a prescription drug, denoted as NDA 21-180. Defendants otherwise deny the allegations contained in Paragraph 30 of the Complaint.

31. Defendants admit that the NDA provides for the prescription use of ORTHO EVRA® for the prevention of pregnancy. Defendants otherwise deny the allegations contained in Paragraph 31 of the Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of the Complaint.

33. Defendants deny the allegations contained in Paragraph 33 of the Complaint.

34. Defendants deny the allegations contained in Paragraph 34 of the Complaint.

35. Defendants deny the allegations contained in Paragraph 35 of the Complaint.

36. Defendants admit that clinical trials were conducted, pursuant to an FDA approved NDA, which were reviewed by the FDA prior to FDA approval of ORTHO EVRA® for the prescription drug use by physicians. Defendants otherwise deny the allegations contained in Paragraph 36 of the Complaint.

37. Defendants deny the allegations contained in Paragraph 37 of the Complaint.

38. Defendants deny the allegations contained in Paragraph 38 of the Complaint.

39. To the extent that Paragraph 39 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 39 of the Complaint.

40. To the extent that Paragraph 40 of the Complaint refers to a document, Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 40 of the Complaint.

41. In response to Paragraph 41, Defendants admit that the contraceptive product known as ORTHO EVRA® received approval from the Food and Drug Administration as a prescription drug on or about November 20, 2001. Defendants otherwise deny the allegations contained in Paragraph 41 of the Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of the Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.

44. To the extent that Paragraph 44 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that document for a fair and

accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 44 of the Complaint.

45. To the extent that Paragraph 45 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 45 of the Complaint.

46. To the extent that Paragraph 46 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 46 of the Complaint.

47. To the extent that Paragraph 47 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 47 of the Complaint.

48. Defendants deny the allegations contained in Paragraph 48 of the Complaint.

49. Defendants deny the allegations contained in Paragraph 49 of the Complaint.

50. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 50 of the Complaint.

51. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 51 of the Complaint.



52. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 52 of the Complaint.

53. Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 53 of the Complaint.

54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.

55. Defendants deny the allegations contained in Paragraph 55 of the Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of the Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of the Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of the Complaint.

59. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 59 of the Complaint.

60. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 60 of the Complaint.

61. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 61 of the Complaint.

62. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 62 of the Complaint.

63. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 63 of the Complaint.

64. To the extent that Paragraph 64 refers to Plaintiff's state of mind, Defendants are



without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 64 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 64 of the Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of the Complaint.

**FIRST CAUSE OF ACTION**  
**(NEGLIGENCE)**

66. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

67. The allegations contained in Paragraph 67 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 68 of the Complaint to the extent they suggest any different or greater duties.

68. Defendants deny the allegations contained in Paragraph 68 of the Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of the Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of the Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

**SECOND CAUSE OF ACTION**  
**(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)**

72. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

73. In response to Paragraph 73 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed,

distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 73 of the Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of the Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of the Complaint.

76. In response to Paragraph 76, Defendants state that Ortho-McNeil intends for the contraceptive product known as ORTHO EVRA® to reach consumers without substantial change in the condition in which it was sold. Defendants otherwise are without sufficient knowledge to form a belief as to the truth of the remaining allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of the Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of the Complaint.

**THIRD CAUSE OF ACTION**  
**(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)**

80. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

81. In response to Paragraph 81 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed, manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 81 of the Complaint.

82. In response to Paragraph 82, Defendants state that Ortho-McNeil intends for the contraceptive product known as ORTHO EVRA® to reach consumers without substantial change in the condition in which it was sold. Defendants otherwise are without sufficient

knowledge to form a belief as to the truth of the remaining allegations contained in Paragraph 82 of the Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of the Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of the Complaint.

**FOURTH CAUSE OF ACTION**  
**(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)**

85. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

86. Defendants deny the allegations contained in Paragraph 86 of the Complaint.

87. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 87 of the Complaint.

88. To the extent that Paragraph 88 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 88 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 88 of the Complaint.

89. The allegations contained in Paragraph 89 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 89 of the Complaint to the extent they suggest any different or greater duties.

90. Defendants deny the allegations contained in Paragraph 90 of the Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of the Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.



93. To the extent that Paragraph 93 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 93 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 93 of the Complaint.

94. The allegations contained in Paragraph 94 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 94 of the Complaint to the extent they suggest any different or greater duties.

95. To the extent that Paragraph 95 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 95 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 95 of the Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of the Complaint.

**FIFTH CAUSE OF ACTION**  
**(BREACH OF EXPRESS WARRANTY)**

97. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

98. Defendants deny the allegations contained in Paragraph 98 of the Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of the Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of the Complaint.

101. To the extent that Paragraph 101 refers to the state of mind of others, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations



in Paragraph 101 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 101 of the Complaint.

102. To the extent that Paragraph 102 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 102 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 102 of the Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of the Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of the Complaint.

**SIXTH CAUSE OF ACTION**  
**(BREACH OF IMPLIED WARRANTIES)**

105. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

106. In response to Paragraph 106 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants deny all remaining allegations contained in Paragraph 106 of the Complaint.

107. In response to Paragraph 107 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, developed manufactured, tested, promoted, marketed, distributed and sold the contraceptive product known as ORTHO EVRA®. Defendants deny all remaining allegations contained in Paragraph 107 of the Complaint.

108. To the extent that Paragraph 108 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 108 of the Complaint. Defendants otherwise deny the remaining allegations contained

in Paragraph 108 of the Complaint.

109. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 109 of the Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

**SEVENTH CAUSE OF ACTION**  
**(FRAUDULENT MISREPRESENTATION)**

113. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

114. Defendants deny the allegations contained in Paragraph 114 of the Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of the Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of the Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of the Complaint.

118. To the extent that Paragraph 118 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 118 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 118 of the Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of the Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of the Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of the Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of the Complaint.

**EIGHTH CAUSE OF ACTION**  
**(FRAUDULENT CONCEALMENT)**

124. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

125. Defendants deny the allegations contained in Paragraph 125 of the Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of the Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of the Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of the Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of the Complaint.

130. To the extent that Paragraph 130 refers to the state of mind of others, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 130 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 130 of the Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of the Complaint.

**NINTH CAUSE OF ACTION**  
**(NEGLIGENT MISREPRESENTATION)**

132. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

133. In response to the allegations contained in Paragraph 133 of the Complaint, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 133 of the Complaint to the extent they suggest any different or greater duties.

134. Defendants deny the allegations contained in Paragraph 134 of the Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of the Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of the Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of the Complaint.

**TENTH CAUSE OF ACTION**  
**(VIOLATION OF GBL §§ 349 AND 350)**

138. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

139. In response to the allegations contained in Paragraph 139 of the Complaint, Defendants admit that Ortho-McNeil advertised and sold the contraceptive product known as ORTHO EVRA®. Defendants deny all remaining allegations contained in Paragraph 139 of the Complaint.

140. Defendants deny the allegations contained in Paragraph 140 of the Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of the Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of the Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of the Complaint.

144. Defendants deny the allegations contained in Paragraph 144 of the Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of the Complaint.

**PRAYER FOR RELIEF**

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.



**AFFIRMATIVE DEFENSES**

For further answer to Plaintiff's Complaint, Defendants respectfully aver:

**FIRST AFFIRMATIVE DEFENSE**

Plaintiff's Complaint, or certain counts, fails to state a claim against Defendants upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

If the injuries and damages alleged by Plaintiff in the Complaint were actually sustained, such damages and injuries resulted from a preexisting and/or unrelated medical condition and/or idiosyncratic reaction and not from any act or omission on behalf of Defendants or a defect in ORTHO EVRA®.

**THIRD AFFIRMATIVE DEFENSE**

The injuries and damages alleged by Plaintiff in the Complaint may have been caused, in whole or in part, by the acts or omissions of others for whose conduct Defendants are not responsible.

**FOURTH AFFIRMATIVE DEFENSE**

The injuries and damages alleged by Plaintiff in the Complaint were caused, brought about or contributed to by her own comparative fault, and any recovery by Plaintiff must therefore be reduced proportionately or altogether barred.

**FIFTH AFFIRMATIVE DEFENSE**

The injuries and damages alleged by Plaintiff in the Complaint were the result of an independent, intervening, and/or superseding cause. Any alleged action or alleged omission on the part of Defendants was not the proximate cause of such damages and injuries.

**SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred or reduced by the doctrine of avoidable consequences.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff has failed to obtain jurisdiction over Defendants.

**EIGHTH AFFIRMATIVE DEFENSE**

The United States Food and Drug Administration ("FDA") approved the labeling for ORTHO EVRA®, and the marketing and/or distribution of ORTHO EVRA® conformed with FDA requirements and all other applicable statutes at all times pertinent to the Complaint.

**NINTH AFFIRMATIVE DEFENSE**

Because the FDA approved ORTHO EVRA®, Plaintiff's claims that Defendants are strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

**TENTH AFFIRMATIVE DEFENSE**

The injuries and damages alleged by Plaintiff in the Complaint are or may be due to her assumption of the risk of use of ORTHO EVRA®, if any, thereby barring Plaintiff from recovery.

**ELEVENTH AFFIRMATIVE DEFENSE**

Adequate and complete warnings and instructions were provided with ORTHO EVRA®. ORTHO EVRA® was neither defective nor unreasonably dangerous when used according to label instructions.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of express or implied warranty are barred by Plaintiff's failure to give notice.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of warranty are barred by the absence of privity of contract between Plaintiff and Defendants.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Defendants are entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions or labeling of ORTHO EVRA® were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the Learned Intermediary Doctrine, or the Informed Intermediary Doctrine and/or the principle of Restatement (Second) of Torts § 388.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including ORTHO EVRA®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims, in whole or in part, are preempted expressly and impliedly by the Supremacy Clause of the Constitution of the United States of America and by applicable federal statutes and regulations thereunder.

**NINETEENTH AFFIRMATIVE DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001).

**TWENTIETH AFFIRMATIVE DEFENSE**

If Defendants are found liable to Plaintiff for any non-economic loss, as defined in Article 16 of the New York Civil Practice Law and Rules, and such liability equals 50% or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds 50% of the total liability, Defendants' liability, if any, to Plaintiff for a non-economic loss shall not exceed Defendants' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

The awarding of punitive damages and Plaintiff's claims for punitive damages are unconstitutional under the constitutions of the United States and the State of New York. The awarding of punitive damages would be unconstitutional because punitive damages are a punishment, a quasi-criminal sanction for which Defendants have not been afforded the specific procedural safeguards prescribed in the New York Constitution as well as the Fifth and Sixth



Amendments to the United States Constitution, and would violate constitutional proscriptions against excessive fines.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996); Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); State Farm Mutual Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003); and Philip Morris USA v. Williams, 549 U.S. \_\_\_, 127 S. Ct. 1057 (2007), together with all such standards applicable under New York law.

#### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the First Amendment of the Constitution of the United States and Article I, Section 8 of the Constitution of the State of New York.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries and damages alleged by Plaintiff in the Complaint pursuant to Section 15-108 of the General Obligation Law.

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations or repose, or by operation of laches.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's causes of action are barred in whole or in part by the doctrines of waiver and equitable estoppel.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Any damages allegedly recoverable by Plaintiff should be reduced in accordance with Rule 4545 of the New York Civil Practice Law and Rules.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because Defendants did not owe any legal duty to Plaintiff or, if Defendants did owe such a legal duty, Defendants did not breach that duty.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by her abuse and/or misuse of the ORTHO EVRA® product.

**THIRTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims must be dismissed because venue in the United States District Court for the Southern District of New York is not proper as the Southern District of New York is an inconvenient forum for the parties.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff has failed to plead fraud and/or misrepresentation with the particularity requirements under Rule 9(b) of the Federal Rules of Civil Procedure.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

To the extent not incorporated above, Defendants raise all affirmative defenses available under the law of the forum in which the alleged cause of action arose.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiff cannot recover under their consumer protection claims because Defendants were

not engaged in consumer oriented conduct as required by the New York consumer protection laws.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's consumer protection claims are preempted by New York law, including N.Y. Gen. Bus. Law § 399.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Defendants specifically deny each and every allegation contained in the Complaint by which liability is sought to be imposed upon it, and give notice that they intend to rely upon such other defenses as may become available or appear during discovery in this case and hereby reserve the right to amend this Answer to assert any such defenses.

WHEREFORE, having fully answered, Defendants request that Plaintiff's Complaint against it be dismissed at Plaintiff's cost and that this Court grant any further relief which it deems just and equitable.

**JURY DEMAND**

Defendants hereby demand a trial by jury of all the facts and issues so triable pursuant to 38(b) of the Federal Rules of Civil Procedure.

Respectfully submitted,

Dated: April 3, 2008

/s/ Patrick G. Broderick  
Robert W. Sparks (RS 4250)  
Debra D. O'Gorman (DO 1643)  
Patrick G. Broderick (PB 7282)  
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New York, NY 10112-2200  
(212) 698-3500  
Email: patrick.broderick@dechert.com

**Attorneys for Defendants**



**CERTIFICATE OF SERVICE**

Patrick G. Broderick, an attorney admitted to practice before this Court, hereby affirms under penalty of perjury that on April 3, 2008, I caused a true and correct copy of the foregoing Defendants' Answer, Affirmative Defenses And Jury Demand to be served via electronic case filing upon all parties so registered.

Dated: New York, NY  
April 3, 2008

/s/ Patrick G. Broderick  
Patrick G. Broderick (PB 9556)